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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,445	06/20/2005	Yoshinori Komatsu	Q88710	6821

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SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER

O'HERN, BRENT T

ART UNIT	PAPER NUMBER
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1783

NOTIFICATION DATE	DELIVERY MODE
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06/30/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/539,445	Applicant(s) KOMATSU ET AL.	
	Examiner BRENT T. O'HERN	Art Unit 1783	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/3/2010 has been entered.

Claims

2. Claims 1 and 8 are pending.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

WITHDRAWN REJECTIONS

4. All rejections of record in the Office action mailed 12/8/2009 have been withdrawn due to Applicant's amendments in the Paper filed 6/3/2010.

NEW REJECTIONS

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5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

6. Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. The test of scope of enablement is whether one skilled in the art could make and use the claimed invention coupled with information known in the art without **undue experimentation** (See *United States v. Theketrone Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighing many factors (See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400 and MPEP 2164.01.)

(A) The breadth of the claims:

The above claims are very broad. All of the claims require a valve, discharging nozzle, a gas propellant, an emulsion and no requirement of the type of valve, type of propellant, amount of oil, amount of water or pressure. There are millions of formulations of propellants with the emulsion, millions of water/oil ratios, numerous types of valves to try and numerous container pressures. Furthermore, it is not clear which parameters are critical in creating a foam as opposed to a stream or a mist. See *Follmer* (US 3,896,975) where the same type formula as claimed is not a foam.

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(B) The nature of the invention;

Emulsions are not a very complex type of invention as emulsions have been known for many years. However, there are many different formulations for making emulsions and chemical variations do not always yield predictable results.

(C) The state of the prior art;

Emulsions are in a relatively crowded art since emulsions have been made for many years, especially when compared to cutting edge pharmaceutical or biotech composition technologies.

(D) The level of one of ordinary skill;

The level of ordinary skill in the art is probably a research chemist having a minimum of two or three years of experience.

(E) The level of predictability in the art;

The art is relatively predictable when the number of ingredients is small, however, decreases when the number and type of ingredients increase.

(F) The amount of direction provided by the inventor;

The inventors list some specific ingredients and ranges that will work, however, there are millions of other compositions that may or may not but are nonetheless encompassed by the claim language, thus, undue experimentation is required.

Furthermore, a user is required to access dictionaries and chemical handbooks, etc. to come up with ingredients to experiment with.

(G) The existence of working examples; and

The Specification provides working examples, however, millions more experiments are required to determine whether others within the claim scope will work.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Millions of experiments are required in order to determine what will and will not work. The sheer volume could be considered unduly burdensome but especially so when the interactions of the multiple ingredients are not set forth by applicant, nor well founded in the prior art.

Given the above analysis of the factors, which courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that a skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention. Factors A and H are very significant and weigh heavily in favor of lack of enablement. Applicant is advised to positively set forth, clear and definite structural limitations.

8. Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The phrase “the container has a discharging nozzle for discharging the emulsion with the gas propellant as a foam therefrom” in claim 1, lines 5-8 is vague and indefinite since it is unclear whether any valve will generate a foam with the emulsion or is a specific type of valve required.

Clarification and/or correction required.

Claim Rejections - 35 USC § 103

10. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (US 2003/0019888) in view of Matsuda et al. (US 5,773,073) and Hotta et al. (US 2002/0182303).

Gupta ('888) teaches a container with a discharge nozzle and propellant (See *paras. 97, 49-53.*) including a foamable water-in-oil type emulsion product such as edible spreads, butter/margarine, oil sprays and mousses wherein the foam is generated at the time of jetting (See *paras. 97, 49-53 and FIG-1, container #100 with food product. The claims are interpreted as being directed to an emulsion that is capable of being foamed and not a foamed emulsion.*), which is contained in an aerosol container with a gas propellant (See *paras. 97-98, 49-53, Abstract and FIG-1, aerosol container #100.*), however, fails to expressly disclose wherein the emulsion comprises an emulsifier in the amount of 0.5 to 6.0 wt% based on the emulsion; wherein the oil in the water-in-oil type emulsion is an edible oil which has a cloud point (ASTM) of about 4.4°C (40 °F) or lower, the container comprises a gas propellant partially dissolved in said water-in-oil emulsion), wherein the emulsifier is at least one member selected from the group consisting of monoglycerin fatty acid ester, sucrose fatty acid ester, sorbitan fatty acid ester, and polysorbate and wherein the monoglycerin fatty acid ester, if included, is in the range 2.5-3.0 parts by weight based on the emulsion.

Matsuda ('073) teaches glycerin fatty acid ester, sucrose fatty acid ester, and sorbitan fatty acid ester as being emulsifiers for water in oil emulsions being from 0.1 to 5% (See *col. 3, ll. 56-67 and Abstract.*) for the purpose of providing a water in oil

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emulsion having excellent emulsion stability (*See Abstract and col. 3, ll. 56-67.*).

Regarding the claimed oil, Matsuda ('073) teaches wherein the oils in the emulsion are the same corn, soybean oil and salad oils as disclosed by Applicant (*See col. 3, ll. 31-51. Soybean oil has a cloud point of about 14 °F as Applicant admits at page 6 of Applicant's Paper filed 5/21/2009 where Applicant refers to Table 5.3 of the Bailey's publication.*), thus, it would have been obvious that these oils also have the same cloud point as claimed. Regarding the propellant, it would have been obvious to incorporate a propellant into the emulsion formulation in order to discharge the material as a foam, spread or mousse.

Hotte ('303) teaches where sucrose fatty acid ester and sorbitan fatty acid ester emulsifiers are used individually in the formation of spreads for the purpose of providing a product with improved refrigeration resistance (*See paras. 5, 36 and Abstract.*).

Therefore, it would have been obvious to a person having ordinary skill in the art to substitute the water in oil emulsion as taught by Matsuda ('073) and Hotte ('303) for Gupta's ('888) generic water in oil emulsion in order to provide a water in oil emulsion having excellent emulsion stability.

ANSWERS TO APPLICANT'S ARGUMENTS

- 11.** In response to Applicant's arguments (*See pp. 3-5 of Applicant's Paper filed 6/3/2010.*) regarding Follmer (US 3,896,975), it is noted that said reference is no longer cited, thus, said arguments are moot.
- 12.** In response to Applicant's arguments (*See p. 4, para. 3 of Applicant's Paper filed 6/3/2010.*) that Matsuda ('073) teaches polyglycerol fatty acid ester in addition to the

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emulsifiers as claimed instead of just the emulsifiers as claimed, it is noted that said arguments are not persuasive. The claimed emulsifiers are common (*See Hotte ('303) as discussed above.*) and it is not critical for Gupta's ('888) emulsion to have polyglycerol fatty acid ester as Gupta ('888) oil-in water emulsion is generic. No further precise arguments are set forth.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT T. O'HERN whose telephone number is (571)272-6385. The examiner can normally be reached on Monday-Thursday, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brent T O'Hern/
Examiner, Art Unit 1783
June 26, 2010